

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

_____)	MDL No. 1456
IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	Civil Action: 01-CV-12257-PBS
LITIGATION)	
_____)	Judge Patti B. Saris
)	
THIS DOCUMENT RELATES TO:)	
<i>County of Suffolk v. Abbott Labs., et al.,</i>)	
(E.D.N.Y. No. CV-03-229))	
_____)	

**RESPONSE OF THE SUFFOLK 13 + 6 CHALLENGING
SUFFOLK COUNTY'S SUPPLEMENTAL FILING
IN RESPONSE TO THE COURT'S OCTOBER 26, 2004 ORDER**

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I. PRELIMINARY STATEMENT

In its October 26 Order, the Court deferred ruling on the individual motions to dismiss of “the Suffolk 13 and those other defendants for whom Suffolk has not alleged specific facts beyond a spread.” *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, No. 03-CV-10643, Memorandum and Order, dated Oct. 26, 2004 at 4 (the “Order”). This memorandum is filed on behalf of those defendants, referred to herein as the “Suffolk 13 + 6”.¹

This Court ordered Suffolk County (“Suffolk”): (1) to “disclose within three weeks all documents upon which it relied in calculating the spreads”; and (2) to “provide, in writing, a more definite statement of its method of calculation pursuant to Federal Rule of Civil Procedure 12(e).” *Id.* The stated intent of the Court was to require Suffolk to provide a good faith basis for keeping in the case those defendants against whom Suffolk has been unable to come up with any allegations other than an alleged “spread.” Suffolk instead has cobbled together an explanation for its definition of a “true” AWP that relies on a flawed industry average which is, by definition, not based on information specific to any defendant. Suffolk then compounds its error by applying a multiplier that the government itself has cautioned should not be relied upon in this manner. Suffolk’s supplemental submission demonstrates that Suffolk has no good faith basis for its allegations of supposed spread and mandates dismissal of these defendants.²

¹ The original Suffolk 13 are Defendants Agouron Pharmaceuticals, Inc., Barr Laboratories, Inc., Berlex Laboratories, Inc., Biogen, Inc., Eli Lilly and Company, Forest Pharmaceuticals, Inc., Genentech, Inc., Ivax Corporation and Ivax Pharmaceuticals, Inc., MedImmune, Inc., Merck & Co., Inc., Purdue Pharma, L.P., Reliant Pharmaceuticals, and Sanofi-Synthelabo Inc. Defendants Purdue Pharma, Ivax Corporation, Ivax Pharmaceuticals, and Sanofi-Synthelabo were dismissed by the Court and thus have not joined in this response. The additional 6 defendants are: Amgen Inc., Chiron Corp., Fujisawa Healthcare, Inc., Johnson & Johnson, Warrick Pharmaceuticals, and Wyeth. Certain of the defendants are also submitting brief separate memoranda addressing defendant-specific points.

² Interestingly, Suffolk’s submission also demonstrates a vastly different method of calculating “spread” when compared to the MDL private plaintiffs.

Suffolk's failure to provide a calculation that provides a good faith basis for its allegations of a fraudulent "spread" is apparent from the following defects in its methodology:

- Suffolk's calculation of so-called "average retail prices" is not based on any genuine average of retail prices;
- Suffolk's use of a 1.27 multiplier to calculate its "estimated true AWP" lacks both a factual basis and methodological credibility:
 - The 1.27 figure is based upon a footnote in a Canadian article which had nothing to do with AWP, and focused instead on a comparison of drug prices in Canada and the United States based on a limited survey that fails to include a majority of the drugs referenced in Suffolk's Amended Complaint;
 - The HHS study to which the article cites for this proposition contains no mention of this 1.27 multiplier nor does it provide any express calculation from which the multiplier may be derived;
 - The HHS study specifically notes that the pharmaceutical prices it cites are illustrative only and are not industry-wide averages; and
 - The article relied upon fails to consider many, if not most, of the drugs at issue in this case.

Additionally, Suffolk's supplemental submission fails to comply with the Court's Order in that Suffolk has not provided all of the documents on which it relied in making its spread calculations. What is more, many of the documents Suffolk *has* provided cannot support Suffolk's allegations, because they post-date the filing of the Amended Complaint. Finally, Suffolk inappropriately seeks to use its submission as an opportunity to add "additional information" about some defendants. Wholly apart from the irrelevance of the information alleged, this Court's prior rulings require that such information, which is from outside the complaint, be disregarded.

II. ARGUMENT

The defects in Suffolk's calculations are addressed in detail below. In considering these details, however, the Court should not lose sight of the most conspicuous feature of Suffolk's

filing: No one could possibly read the article and other documents attached to Suffolk's filing without realizing that published AWP's are not and were not understood by anyone to represent an actual average of actual wholesale prices.

A. Suffolk County's Methodology In Calculating The Alleged Spread Cannot Serve As A Good Faith Basis For Keeping The Suffolk 13 + 6 In This Case

1. Suffolk's Asserted Method of Calculating Spreads

Suffolk's explanation for how it comes up with a spread, is as follows:

- Citing to a footnote in an article attached to its supplemental papers, Suffolk claims "[i]n the United States the average retail price is estimated to be 1.27 times the true average wholesale price." Affidavit of Aaron D. Hovan, sworn to Nov. 16, 2004 ("Hovan Aff."), ¶3.
- Suffolk purports to have gathered retail prices by "survey[ing]" three "independent sources," which actually amounted to nothing more than perusing the websites of three pharmaceutical retailers. *Id.* ¶¶4-5 and n. 5.
- Suffolk next purports to have derived a "conservative average retail price" by averaging, where available, retail prices from these three sources. *Id.* ¶5.
- Suffolk then claims it divided this "conservative average retail price" by its 1.27 figure to arrive at the "estimated true AWP". *Id.* ¶6. The "estimated true AWP" was then compared to published AWP's to derive the supposed spread. *Id.* ¶7.

2. Suffolk Miscalculates "Average Retail Prices"

The first fundamental flaw in Suffolk's calculation is that the methodology Suffolk uses to determine the "average retail price" is both unprincipled and unreliable:

- Suffolk purports to rely on an "average retail price" based upon three Internet sources – drugstore.com, Costco.com, and Eckerd.com., each of which sells some, but not all, of the drugs at issue in this case. Suffolk provides no explanation of why these three sources were chosen or why other sources were not chosen.
- Suffolk then uses those websites to determine prices for certain products in the years 2003 and 2004, after its Amended Complaint was filed.

- Suffolk never explains how this limited sampling of 2003 and 2004 prices can possibly support claims for a period prior to 2001.

Indeed, all that can be gleaned from the material submitted by Suffolk is that in 2003 and 2004 a particular drug might have been sold by a particular retailer, at a particular price at some undefined point in time, for an undefined period of time.

Suffolk provides no basis for inferring (much less concluding) that the prices derived from three arbitrarily chosen websites are average or even representative retail prices. In fact, at least one of the websites relied upon by Suffolk provides an express disclaimer. It notes that the prices quoted are for Internet orders only, suggesting that the price – even for that retailer – does *not* represent the actual retail price for the drug, but lower than the average. *See* www.familymeds.com (stating “Prices valid for Internet orders only.”). Without more, the individual prices relied upon by Suffolk have no meaning, and “averaging” these random prices merely compounds the problem.

Suffolk’s method of extrapolating an “average” retail price is equally flawed. For some drugs, Suffolk appears to have used only one source to calculate an “average retail price”. *See, e.g.,* Ex. C (Effexor, Prograf & Pulmozyme); Ex. D (Clozapine, Tobi solution & Zyprexa (1.5 MG and 20 MG)). An industry-wide “average retail price” cannot be based upon one data point – or even three data points. Arbitrary calculations cannot serve as a foundation for dragging these defendants into a lawsuit accusing them of fraud.

Suffolk’s determination of “average retail prices” has other major problems. For reasons Suffolk does not explain, its 2004 retail prices were not based upon a sampling from the same three Internet websites used to calculate the 2001 retail prices.³ Moreover, Suffolk altogether

³ Suffolk dropped Eckerd.com and replaced it with familymeds.com.

fails to state the basis for the prices it used to calculate the 2003 “average retail prices” set forth in Exhibit C to its submission. And although Suffolk’s Amended Complaint alleges that the so-called “AWP” scheme commenced in 1993 or earlier, Suffolk’s submission presents no information whatsoever regarding an alleged “spread” for any year prior to 2001.

Suffolk’s manipulation of the data is as suspect as its method of collection. Suffolk, for example, admits that in some cases, its retail prices are not based upon a true like-to-like comparison of product type and price. Hovan Aff. ¶5. In particular, Suffolk states that, when it could not match unit pricing across its three pricing sources, it simply manipulated the prices until it created a common unit basis for comparison. *Id.* Such manipulation is clearly inappropriate.⁴ Further compounding the problem, Suffolk does not identify the drugs for which it calculated its own unit price. Accordingly, these Defendants cannot address any errors made in performing those calculations.

3. Suffolk’s 1.27 “Ratio” Is Fundamentally Flawed

Suffolk’s claims depend upon taking this shapeless collection of so-called “average retail” prices and multiplying them by an entirely arbitrary multiplier. But the 1.27 multiplier Suffolk uses to convert its “average retail price” into its “estimated true AWP” is hopelessly inadequate as a good faith basis for Suffolk’s spread calculation.

The sole source for the 1.27 multiplier – which serves as the foundation of Suffolk’s assumption that retail prices are necessarily 27% higher than wholesale prices – is a casual statement in a footnote of a non-peer-reviewed article comparing drug prices in Canada and the United States that the “average retail price in the United States is 1.27 times the true average

⁴ Indeed, the very article upon which Suffolk relies recognized the insidiousness of this problem and only compared drugs using “the most common dose, form and package of the drug, so long as it was identical in the two countries.” Hovan Aff., Ex. J, Analysis at 5.

wholesale price.” *See* Hovan Aff., Ex. J, Notes at n.1. The footnote, in turn, cites an April 2000, HHS Report to the President entitled, “*Prescription Drug Coverage, Spending, Utilization, and Prices*” (“HHS Report”)[at page 98] as the basis for its statement. *Id.* But the HHS Report does not support this citation. Nowhere in the more than 100 pages of the HHS Report is there any mention of the 1.27 multiplier, nor any readily identifiable basis from which the 1.27 figure can be derived.

In addition, the HHS Report expressly cautions that it cannot be used as a source for an actual average of retail prices (as Suffolk is attempting to do here), stating, in pertinent part: “[t]hese prices are used for illustrative purposes only and do not represent any type of overall average.” HHS Report, Chapter 3 at 3, *available at* <http://aspe.hhs.gov/health/reports/drugstudy/chap03.htm>. The HHS Report further states, in the very section on which the Canadian article appears to have relied, that its figures are derived as “illustrative pricing for brand name drugs” and that “[a]ctual price relationships vary substantially by drug.” *Id.* at Table 3-1. Thus, the only support for this critical element of Suffolk’s spread calculations boils down to an unwarranted assumption, from an apparently incorrect reading of another article, included as a passing reference in a footnote of a non-peer-reviewed article. Such a slim reed cannot provide the “good faith basis” the Court required as a support for Suffolk’s claims.

Finally, Suffolk’s reliance on the Canadian article is misplaced because the article fails to consider the vast majority of the drugs at issue here. Since the article limits its analysis to the 60 drugs most commonly prescribed in 1998, it excludes – from the outset – more than two-thirds of the drugs Plaintiffs list in their Amended Complaint. *Compare* Hovan Aff., Ex. J, Method at 1 and Ex. 1 (describing sample) *with* Suffolk Am. Complaint, Ex. A (listing 67 drugs, 49 of which

are not included in the top 60 drugs from 1998). Moreover, the article specifically excludes six of the drugs at issue here. *See* Hovan Aff., Ex. J, Method at 2 (excluding Albuterol[®] Aerosol, Ambien[®], Clartitin[®], Glucotrol XL[®], and Ultram[®] from both retail and wholesale price comparisons) and Hovan Aff. Ex. J, Analysis at 4 (explaining the basis for excluding Epogen[®]). Apart from providing a slim reed for the "1.27 ratio," the Canadian article specifically excludes 54 of the 67 drugs listed by Suffolk County.

B. Suffolk Has Failed To Provide Defendants With All Of The Documents On Which It Relied In Calculating The Spread And The Documents It Does Provide Could Not Have Been Relied Upon In Calculating The Spread

Suffolk has not followed the Court's Order to provide "all documents upon which it relied in calculating the spreads." Order at 4. The only documents Suffolk produced in response to the Court's Order are several spreadsheets authored by its counsel and some publicly available documents relating to a single drug, Albuterol[®]. Despite the Court's Order to produce "*all documents* upon which it relied in calculating the spread," Suffolk provides no other documents to support its calculation of any alleged spread for any other product.⁵ *Id.* (emphasis added). Its failure to do so masks deficiencies with the calculations of individual product spreads, prevents defendants from challenging the calculation methodology for particular spreads and calls into question whether the process described by Suffolk was followed for every drug.

Suffolk also claims to have "confirmed" with Professor Steven Schondelmeyer⁶, Andy Schneider, Esquire, and unidentified "others", the "reasonableness" of using the 1.27 multiplier.

⁵ Suffolk County concedes that it did not provide "every *Redbook* entry on which it relied to calculate an estimated spread for the Suffolk 2001 drugs" and offers to "supplement" its submission "in that or any other regard if the Court so desires." Hovan Aff. at 4 n.6. The Court has already ordered Suffolk to provide all documents on which it relied in calculating the spreads. The absence of these documents is proof of Suffolk's lack of a good faith basis for its claims.

⁶ Professor Schondelmeyer was first identified as an expert in the MDL proceedings on August 31, 2004, when he submitted an expert report in support of MDL plaintiffs' motion for Class Certification.

Hovan Aff. ¶ 3. Suffolk, however, provides no documents demonstrating: (i) that these supposed conversations took place prior to the filing of the Amended Complaint (and thus were relied upon by Suffolk in calculating spreads); (ii) that Professor Schondelmeyer, Mr. Schneider, or others provided Suffolk with opinions that actually support Suffolk's allegations; (iii) that these individuals are qualified to provide such a "confirmation"; (iv) an explication of their opinions; or (v) the bases for any such opinions. Without such information, it is impossible to determine if Suffolk relied upon these individuals in calculating the spread as it contends, whether these individuals were consulted after-the-fact to put a veneer of credibility on Suffolk's calculations and whether they are qualified to, and in fact support, Suffolk's calculation methodology.

Even more remarkable are the documents that Suffolk has produced, which demonstrate on their face that they could not possibly have been relied upon by Suffolk in drafting its amended complaint. Many of the documents submitted by Suffolk post-date the filing of its Amended Complaint. For example, exhibits H, I, and J all clearly indicate on their face that they were printed from the Internet and presumably reflect pricing information in effect in November 2004 – well *after* the July 31, 2003 filing of Suffolk's Amended Complaint and only days before the filing of its supplemental papers. The exhibits supposedly illustrating Suffolk's pre-complaint investigation and calculation of estimated spreads are dated 8/4/03, 11/5/04, 11/8/04, and 11/11/04 – all after the date on which Suffolk filed its Amended Complaint. These dates cast serious doubt upon the validity of other documents upon which Suffolk claims to have relied such as Exhibit D, upon which Suffolk claims to have also relied in calculating the "estimated overcharges" for purposes of its Amended Complaint. This document, in turn, relies upon documents contained in Exhibit I, which were generated over a year after Suffolk filed its Amended Complaint.

C. This Court Should Disregard Suffolk's Improper Attempt To Submit "Additional Information Regarding Defendants"

The Court's Order required Suffolk to provide all documents on which it relied in calculating the spread and to provide a more definite statement regarding its method of calculating spreads. *See* Order at 4. The Court did not grant Suffolk leave to use this filing to seek to otherwise bolster its allegations against certain defendants, which the Court has already found to be lacking. Yet, this is precisely what Suffolk has attempted to do in submitting its "additional information regarding defendants." Suffolk devotes a full eight pages and one exhibit, Exhibit A, of the twelve-page Hovan Affidavit to this subject. The last eight pages of the Hovan Affidavit and Exhibit A should be disregarded. They are not contemplated by the Court's Order and, moreover, do nothing to rectify the problems with Suffolk's Amended Complaint.⁷ *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, No. 01-CV-12257, Memorandum and Order, dated June 9, 2004 (allowing Mot. for Reconsideration) ("I decline to consider documents not referenced in the complaint."); *see also Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993); *Jonker v. Kelley*, 268 F. Supp. 2d 81, 84 (D. Mass. 2003) (recognizing that "Plaintiff is confronted with a significant procedural hurdle, i.e., the general inability of the court to look beyond the four corner's [sic] of the complaint in resolving Defendants' motion to dismiss" and precluding use of such materials in opposition); *Shabazz v. Cole*, 69 F. Supp. 2d 177, 185 (D. Mass. 1999) (same); *McGrath v. MacDonald*, 853 F. Supp. 1, 3 (D. Mass. 1994) (same).

⁷ Moreover, in a highly suspect display of circular reasoning, Suffolk relies on follow-on lawsuits brought on behalf of three other New York jurisdictions (Rockland County, Westchester County and New York City) by the same counsel that represents Suffolk and using cookie-cutter complaints, as evidence of "other allegations" that ostensibly support the claims in the Suffolk County action. Indeed, these follow-on complaints are the *only* "additional information" raised against some defendants, including Agouron, Berlex, Biogen and MedImmune.

III. CONCLUSION

For the foregoing reasons, the “Suffolk 13 + 6” defendants request that the Amended Complaint be dismissed with prejudice, as to them.

Respectfully submitted,

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